UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: February 6, 2008

SUBJECT: Efficacy Review for Maquat 710-HF, EPA Reg. No. 10324-159;
DP Barcode: D346753

FROM: Lorilyn M. Montford 2/6/08
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APPLICANT: Mason Chemical Company
721 Algonquin road
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FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Octyl Decyl Dimethyl Ammonium Chloride	3.0%
Didecyl Dimethyl Ammonium Chloride	1.5%
Dioctyl Dimethyl Ammonium Chloride	1.5%
Alkyl (C_{14}, 50%; C_{12}, 40%; C_{16}, 10%) dimethyl benzyl ammonium chloride	4.0%
Inert Ingredient(s):	90.0%
Total	100.0%

I BACKGROUND

The product, Maquat 710-HF (EPA Reg. No. 10324-159), is an Agency approved disinfectant (bactericide, virucide), sanitizer, and deodorizer for use on hard, non-porous surfaces in household, institutional, industrial, commercial, food processing, animal care, and hospital or medical environments. The label claims that the product is effective in the presence of 5% serum. The applicant requested to amend the registration of this product to add foaming disinfectant claims. The applicant also requested to add disinfectant claims against Infectious bronchitis virus and Transmissible gastroenteritis. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated November 1, 2007), EPA Form 8570-4 (Confidential Statement of Formula), five studies (MRID 472694-01 through 472694-05), Statements of No Data Confidentiality Claims for all five studies, and the proposed label.

II USE DIRECTIONS

The product is designed for treating hard, non-porous surfaces such as appliance exteriors, bathtubs, bed frames, cabinets, cages, carts, chairs, countertops, desks, doorknobs, floors, garbage cans, kennels, lifts, outdoor furniture, racks, shelves, shower curtains, shower doors, shower stalls, sinks, tables, telephone booths, telephones, toilets, urinals, washable walls, and window sills. The proposed label indicates that the product may be used on hard, non-porous surfaces including: enamel, Formica®, glass, glazed ceramic, glazed porcelain, glazed tiles, granite, marble, metal (e.g., chrome, stainless steel), painted woodwork, plastic, sealed concrete, sealed limestone, sealed slate, sealed stone, sealed terra cotta, sealed terrazzo, and vinyl. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Prepare a use solution by adding 1 ounce of product per 1 gallon of water (a 1:128 dilution). Apply the use solution using a cloth, mop, mechanical spray device, or foaming device. Treated surfaces must remain wet for 10 minutes. Allow to air dry. For heavily soiled areas, a preliminary cleaning is required.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Confirmatory Efficacy Data Requirements)

Under certain circumstances, an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on his own product to demonstrate his ability to produce an effective formation. This includes a minor formulation change (e.g., a change in an inert ingredient) in a registered product. Confirmatory data must be developed on the applicant's own finished product. For hospital disinfectants, 10 carriers on each of 2 samples representing 2 different product lots must be tested against *Salmonella enterica* (ATCC 10708; formerly

Salmonella choleraesuis), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442) using either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Killing on all carriers is required. These Agency standards are presented in DIS/TSS-5.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. This Agency standard is presented in DIS/TSS-2.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 472694-01 "AOAC Germicidal Spray Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Maquat 710-HF, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – August 20, 2007. Project Number A05206.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Two lots (Lot Nos. 1621-240 and 1621-241) of the product, Maquat 710-HF, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. Use solutions were prepared by adding 2 mL of the product and 254 mL of filtered sterilized deionized water (a 1:128 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 10 µL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were

sprayed (3 pumps; using a foaming spray bottle) at a distance of 2-3 inches from the carrier surface. Following application, each carrier was placed upright at a 45-90° angle. Each carrier was exposed to the use solution for 10 minutes at 23°C at 52% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

2. MRID 472694-02 "AOAC Germicidal Spray Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Maquat 710-HF, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – August 20, 2007. Project Number A05207.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Two lots (Lot Nos. 1621-240 and 1621-241) of the product, Maquat 710-HF, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. Use solutions were prepared by adding 2 mL of the product and 254 mL of filtered sterilized deionized water (a 1:128 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 10 µL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (4 pumps; using a foaming spray bottle) at a distance of 2-3 inches from the carrier surface. Following application, each carrier was placed upright at a 45-90° angle. Each carrier was exposed to the use solution for 10 minutes at 23°C at 52% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: ATS Laboratory Protocol No. MC03051407.GS.2, included as part of the laboratory report, is marked as "Proprietary Information."

3. MRID 472694-03 "AOAC Germicidal Spray Method, Test Organism: *Salmonella enterica* (ATCC 10708)" for Maquat 710-HF, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – August 20, 2007. Project Number A05208.

This study was conducted against *Salmonella enterica* (ATCC 10708). Two lots (Lot Nos. 1621-240 and 1621-241) of the product, Maquat 710-HF, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. Use solutions were prepared by adding 2 mL of the product and 254 mL of filtered sterilized deionized water (a 1:128 dilution). Fetal bovine serum was added to

the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 10 µL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (3 pumps; using a foaming spray bottle) at a distance of 2-3 inches from the carrier surface. Following application, each carrier was placed upright at a 45-90° angle. Each carrier was exposed to the use solution for 10 minutes at 23°C at 52% relative humidity. Following the exposure period, the remaining liquid was drained off. Individual carriers were transferred to 20 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

4. MRID 472694-04 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Infectious Bronchitis virus" for Maquat 710-HF, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – April 5, 2007. Project Number A04764.

This study was conducted against Infectious bronchitis virus (Strain Beaudette IB42; obtained from Solvay Animal Health), using embryonated chicken eggs (obtained from Charles River SPAFAS) as the host system. Two lots (Lot Nos. 1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Lab Protocol No. MC03022807.IBV (copy provided). Use solutions were prepared by adding 1 mL of the product and 127 mL of filter sterilized deionized water (a 1:128 dilution). The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.1°C at 48% relative humidity. For each lot of product, separate dried virus films were exposed to 2.0 mL of each use solution for 10 minutes at 20.1°C. After the contact period, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephadex columns, and diluted serially in sterile phosphate buffer. Ten-day old fertilized embryonated chicken eggs were inoculated intra-allantoically in quadruplicate with 0.1 mL of the dilutions. The eggs were incubated for 4 days at 34-38°C at 40-80% relative humidity. The eggs were candled daily to determine embryo viability. Eggs containing dead embryos were discarded. Following incubation, viable embryos were considered negative for the test virus. Deaths of embryos less than 24 hours post incubation were not used in the calculation of viral titers. Controls included those for dried virus count, toxicity, and neutralization. Viral and toxicity titers were calculated by the method of Spearman Karber.

5. MRID 472694-05 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Transmissible Gastroenteritis" for Maquat 710-HF, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – April 10, 2007. Project Number A04815.

This study was conducted against Transmissible gastroenteritis (obtained from the

University of Minnesota) using cultures of ST cells (porcine fetal testis cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.TGE (copy provided). Use solutions were prepared by adding 1 mL of the product and 127 mL of filter sterilized deionized water (a 1:128 dilution). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 48% relative humidity. For each lot of product, separate dried virus films were exposed to 2.0 mL of the use solution for 10 minutes at 20.0°C. After the contact period, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through individual Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. ST cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: ATS Laboratory Protocol No. MC03022807.TGE, included as part of the laboratory report, is marked as "Proprietary Information."

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (CFU/ Carrier)
		Lot No. 1621-240	Lot No. 1621-241	
472694-01	*Pseudomonas aeruginosa*	0/10	0/10	9.5×10^4
472694-02	*Staphylococcus aureus*	0/10	0/10	4.8×10^5
472694-03	*Salmonella enterica*	0/10	0/10	6.3×10^4

MRID Number	Organism	Results			Dried Virus Control
			Lot No. 1621-232	Lot No. 1621-240	
472694-04	Infectious bronchitis virus	10^{-1} to 10^{-7} dilution	Complete inactivation	Complete inactivation	$10^{5.25}$ LD_{50}/0.1 mL
		LD_{50}/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

MRID Number	Organism	Results			Dried Virus Control
			Lot No. 1621-232	Lot No. 1621-240	
472694-05	Transmissible gastroenteritis	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete Inactivation	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

VI CONCLUSIONS

1. The submitted confirmatory efficacy data support the use of the product, Maquat 710-HF, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 10 minutes at a 1:128 dilution, when dispensed from a foaming spray bottle: Data on slides at an angle

Pseudomonas aeruginosa	MRID 472694-01
Staphylococcus aureus	MRID 472694-02
Salmonella enterica	MRID 472694-03

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Carrier population counts were at least 10^4. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data support the use of the product, Maquat 710-HF, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 10 minutes at a 1:128 dilution:

Infectious bronchitis virus	MRID 472694-04
Transmissible gastroenteritis	MRID 472694-05

Recoverable virus titers of at least 10^4 were achieved. In studies against Infectious bronchitis virus, toxicity was not observed. In studies against Transmissible gastroenteritis, cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

VII RECOMMENDATIONS

1. The proposed label claims that the product, Maquat 710-HF, is an effective foaming disinfectant on hard, non-porous surfaces in the presence of 5% serum for a contact time of 10 minutes at a 1:128 dilution. Confirmatory data provided by the applicant for *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella enterica* support this claim; however the Agency will require submission of confirmatory data for virus, tuberculocidal, and fungicidal claims for future bridging applications (i.e. from liquid to foam application).

2. The proposed label claims that the product, Maquat 710-HF, is an effective virucide on hard, non-porous surfaces in the presence of 5% serum against Infectious bronchitis virus and Transmissible gastroenteritis for a contact time of 10 minutes at a 1:128 dilution. Data provided by the applicant support these claims.

3. The proposed label claims that the product may be used on hard, non-porous surfaces including granite and marble. These surfaces are porous. Revise the proposed label as follows:

- On page 3 of the proposed label, change "granite" to read "sealed granite"
- On page 3 of the proposed label, change "marble" to read "sealed marble."